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Why is a treatment aimed at psychosocial factors not effective in patients with (sub)acute low back pain?

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Abstract

Psychosocial factors have been shown to play an important role in the development of chronic low back pain (LBP). In our recently completed cluster-randomized trial we found, however, no evidence of an effect of our minimal intervention strategy (MIS) aimed at psychosocial factors, over usual care (UC) in patients with (sub)acute LBP. To explore the reasons why, this paper presents an evaluation of the processes presumably underlying the effectiveness of MIS. General practitioner (GP) attitude was evaluated by the Pain Attitudes and Beliefs Scale and two additional questions. GP behaviour was evaluated by analysing treatment registration forms and patients' responses to items regarding treatment content. Patients also scored items on satisfaction and compliance. Modification of psychosocial measures was evaluated by analysing changes after 6 and 52 weeks on the Fear Avoidance and Beliefs Questionnaire, the Coping Strategies Questionnaire and the 4-Dimensional Symptom Questionnaire. A total of 60 GPs and 314 patients participated in the study. GPs in the MIS-group adopted a less biomedical orientated attitude than in the UC-group, but were only moderately successful in identification of psychosocial factors. Treatment contents as perceived by the patient and patient satisfaction differed significantly between both groups. Changes on psychosocial measures, however, did not differ between groups. The suboptimal identification of psychosocial factors in the MIS-group and the absence of a relevant impact on psychosocial factors may explain why MIS was not more effective than UC.

Keywords: Low back pain; Psychosocial factors; Process evaluation; Randomised controlled trial; General practice

1. Introduction

Chronic low back pain (LBP) is a major problem in Western countries (Andersson, 1999; Maniadakis and Gray, 2000). As psychosocial factors have been shown to play an important role in the transition from acute to chronic LBP (Pincus et al., 2002), early interventions focussing on these factors are assumed to prevent chronic LBP. Linton and Andersson (2000) showed that in patients with subacute LBP a 6-session cognitive-behavioural group therapy was more effective in reducing sick absence and health care consumption than education only. Von Korff et al. (1998) and Moore et al. (2000) showed that a self-management programme was more effective in reducing functional disability at 6 months follow-up than usual care. Similar results have been demonstrated by Damush et al. (2003) for 12 months follow-up.

LBP is commonly treated in general practice (Van der Linden et al., 2004). Group interventions are, in spite of their positive results, too labour intensive and expensive to offer to all patients consulting their general practitioner (GP) for (sub)acute LBP. An individual minimal psychosocial intervention would be more practicable in this setting. We developed an intervention aimed at identification and modification of psychosocial prognostic factors in patients

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with (sub)acute LBP that can be carried out by a GP. Unfortunately, our recently completed cluster-randomised controlled trial showed that this Minimal Intervention Strategy (MIS) was not more effective than usual care (UC) in reducing functional disability, lack of recovery and sick-leave due to LBP (Jellema et al., 2005). To explore why MIS was not more effective than UC, this paper presents an evaluation of the processes presumably underlying its effectiveness. We included those processes that we consider as conditions for demonstrating effectiveness of MIS over UC.

The first condition regards GP attitude. GPs in the MIS-group should have a positive attitude towards the training sessions and the new strategy, as well as obtain a more behavioural and less biomedical orientated attitude towards LBP and its treatment. The second condition concerns GP behaviour. GPs in the MIS-group should be successful in the identification of psychosocial factors like fear avoidance, pain catastrophising and distress, and provide evidence-based care with respect to advice and referral. The third condition regards patient satisfaction (Deyo et al., 1998; Bombardier, 2000) and compliance. The final condition concerns the modification of psychosocial factors. Our theory on the working mechanisms of MIS was that identification and discussion of psychosocial factors would lead to modification of these factors, eventually leading to better functioning. Although we knew that MIS did not result in better functioning compared to UC (Jellema et al., 2005), it was still unknown whether identification and discussion of psychosocial factors would lead to modification of these factors. We therefore, explored whether patients in the MIS-group improved more on fear avoidance, pain catastrophising or distress than patients receiving UC.

2. Methods

2.1. Description

2.1.1. Randomisation and training sessions

Randomisation took place at the level of the general practice. GPs were informed about their allocation after giving final consent to participation. A total of 20 practices (28 GPs) were randomised to the MIS-group and 21 practices (32 GPs) to the UC-group.

The GPs randomised to the MIS-group received two training sessions of 2.5 h given by a GP (HEvdH) with extensive expertise in the development of psychosocial interventions and training of GPs. During the training sessions GPs were informed about the role of psychosocial factors in LBP and about how to identify and discuss these factors during a consultation. The GP practiced this by role-playing and received feedback on the practiced skills. We asked the GPs to practice the new strategy during the 2 weeks in between the training sessions and to report on their efforts in the second session. In the second session the GPs received feedback on their experiences of the last 2 weeks, practiced those elements of the new strategy that they perceived as difficult, and received information on how to deal with extremely worried patients.

2.1.2. Patient recruitment

GPs were asked to select the first 10 patients who consulted them for LBP. Inclusion criteria were: age 18–65; non-specific LBP as main complaint; duration of LBP less than 12 weeks or an exacerbation of persisting back pain; sufficient knowledge of the Dutch language. Exclusion criteria were: LBP caused by specific pathological conditions (metastasis, osteoporosis, rheumatoid arthritis, or fracture); LBP currently treated by another healthcare professional than their GP; pregnancy. Patients were kept unaware that two interventions for LBP were compared. This study was approved by the Medical Ethical Committee of the VU University Medical Center, Amsterdam, The Netherlands.

2.1.3. Treatment: MIS

The MIS was aimed at identification and discussion of psychosocial prognostic factors. Main sources used for the development of this new strategy were a document on the assessment and management of angry and distressed LBP patients (Main and Watson, 2002), a systematic review of psychological factors as predictors of chronicity/disability (Pincus et al., 2002), and the New Zealand Guidelines for LBP (Kendall et al., 1997).

When a patient was interested in participation the GP gave a general advice, prescribed pain medication if necessary, and made an appointment for a second consultation, the MIS consultation. In-between these consultations the informed consent procedure and baseline assessment took place. The MIS consultation took about 20 min and consisted of 3 phases. The content of these phases was printed on registration forms. Firstly, in the exploration phase, the GP explored the presence of psychosocial prognostic factors by asking standardised questions that could be rephrased to fit the style of communication of GP and patient. The topics concerned the patient's own ideas on the cause of the LBP, fear avoidance beliefs, worries regarding the pain, pain catastrophising, pain behaviour and reactions from the social environment regarding the LBP. The GP started by asking a main question, which was usually an open question (we adapted the questions from Main and Watson, 2002). When the patient's response gave the impression that this factor could be an obstacle to recovery, the GP explored the problem further with additional questions, but when the factor did not seem to be an obstacle, the GP continued with the main question of the next factor. Secondly, in the informational phase, the GP provided general information about causes of LBP, prognosis, and (im)possibilities of diagnostic testing and therapy, and included herewith the patient's cognitions, emotions and behaviour. Specific attention was given to psychosocial factors identified in the exploration phase. Finally, in the self-care phase, the GP and patient set specific goals with regard to resuming activities and/or work. Pain medication was discussed and a booklet was handed over to the patient (Pijn Kennis Centrum, 2000). The booklet was based on the Back Book (Royal College of General Practitioners, 1996) and its content reinforced that of the informational phase. Finally, the GP could make an appointment for a follow-up visit if he/she expected persistent LBP-related disability. GPs in the MIS-group were explicitly asked not to refer to exercise therapy, manual therapy, or physiotherapy in the first 6 weeks.

2.1.4. Treatment: UC

During the consultation the GPs in the UC-group provided care as usual. Within a few days the patient was visited by a research assistant for informed consent and baseline assessment. We did not protocolise the content and number of UC consultations, and assumed that GPs would follow the guideline for LBP of the Dutch College of General Practitioners (Faas et al., 1996). For acute LBP this guideline advises a wait-and-see policy with pain medication and gradual uptake of activities. For subacute LBP (>6 weeks) the guideline advises referral for exercise therapy, physiotherapy, or manual therapy in case of persistent functional disability. Explicit guidance on psychosocial factors is lacking.

3. Measures

3.1. GP attitude

GPs in the MIS-group gave their opinion on a 4-point Likert scale (1=completely disagree, 4=completely agree) regarding two statements: 'I think this newly learned treatment strategy is a valuable strategy to apply to patients with LBP' and 'By participating in the two training sessions I have received sufficient skills to apply the newly learned treatment strategy'. These statements were scored twice: directly after the second training session and after the recruitment period (about eight months later).

To evaluate the (change of) the GP attitude regarding LBP we used a slightly modified version of The Pain Attitudes and Beliefs Scale (PABS) for physiotherapists (Ostelo et al., 2003). The PABS consists of 20 items and 2 subscales: a 14-item 'Biomedical Orientation' (14–84) and a 6-item 'Behavioural Orientation' (6–36). GPs scored the PABS twice: before the start of the training sessions (MIS-group) or recruitment period (UC-group) and after the recruitment period.

3.2. GP behaviour

The GP behaviour was evaluated by the GP's performance to identify psychosocial factors, and by the patient perspective of the treatment contents. GPs in the MIS-group were asked to complete treatment forms on which they indicated for each psychosocial factor (ideas on the cause of the LBP, fear avoidance beliefs, worries regarding the pain, pain catastrophising, pain behaviour and reactions from the social environment) whether this factor could be an obstacle to recovery (yes/no). Three of these factors were also assessed in the patients' baseline questionnaires, without the GPs being aware of those scores. Fear avoidance beliefs were assessed by the 4-item physical activity subscale of the Fear Avoidance Beliefs Questionnaire (FABQ, 0–24) (Waddell et al., 1993). Pain catastrophising was assessed by the 6-item subscale of the Coping Strategies Questionnaire (CSQ, 0–36) (Rosenstiel and Keefe, 1983), while distress was measured by the 16-item subscale of the four-dimensional symptom questionnaire (4DSQ, 0–32) (Terluin et al., 2004).

The evaluation of the content of the treatment concerned all GP consultations for LBP in the first 6 weeks after baseline assessment. On a list of possible issue patients indicated which issues had actually been dealt with by the GP (yes/no/?).

3.3. Patient satisfaction and compliance

Patients scored three items regarding their satisfaction with the consultation on a 5-point Likert scale (1=completely disagree; 5=completely agree), and indicated if they had followed the advice of the GP (yes/no) and read the booklet (yes/no; MIS-group only).

3.4. Modification of psychosocial factors

Fear avoidance beliefs, pain catastrophising and distress were evaluated by respectively the FABQ (Waddell et al., 1993), CSQ (Rosenstiel and Keefe, 1983) and 4DSQ (Terluin et al., 2004), and were assessed at baseline, after 6 and 52 weeks.

4. Statistical analyses

4.1. GP attitude

The proportion of GPs that agreed or completely agreed was calculated per statement. For both scales of the PABS change scores were calculated for each individual GP by subtracting baseline scores from those at follow-up. Differences in these change scores between the GPs in both groups were compared by means of analysis of covariance. The baseline values of the PABS were entered as covariate to adjust for differences between groups at baseline.

4.2. GP behaviour

To evaluate if GPs in the MIS-group were successful in the identification of psychosocial factors we performed two analyses. In the first analysis, the mean baseline score on fear avoidance was calculated separately for patients whose fear avoidance beliefs were appraised by the GP as an obstacle to recovery and for those in whom this was not the case. To compare both groups mean differences (MD) and 95% confidence intervals (95% CI) were calculated. The same procedure was followed for pain catastrophising and distress.

In the second analysis, we calculated the sensitivity of the GP appraisal to identify patients with elevated scores on psychosocial factors. Therefore, we had to define cut-off scores. For fear-avoidance we used the median score on the FABQ (>15), which we based on (median) cut-off scores of other studies (Burton et al., 1999; George et al., 2003; Klaber Moffett et al., 2004). For pain catastrophising we

also used the median score on the CSQ (>11), as we lacked information favouring another score. For distress we used a 4DSQ score >10, which is a cut-off validated for the general practice population (Terluin et al., 2004).

To evaluate the contents of the treatment as perceived by the patient, the proportion of patients who indicated that a specific issue had been raised was calculated. The differences between MIS and UC plus 95% CI were calculated

4.3. Patient satisfaction and compliance

Proportions were calculated for patients who (completely) agreed with the items on satisfaction, for patients who reported having followed the advice from their GP, and for those who reported having read the booklet (MIS-group only). The differences between MIS and UC plus 95% CI were calculated.

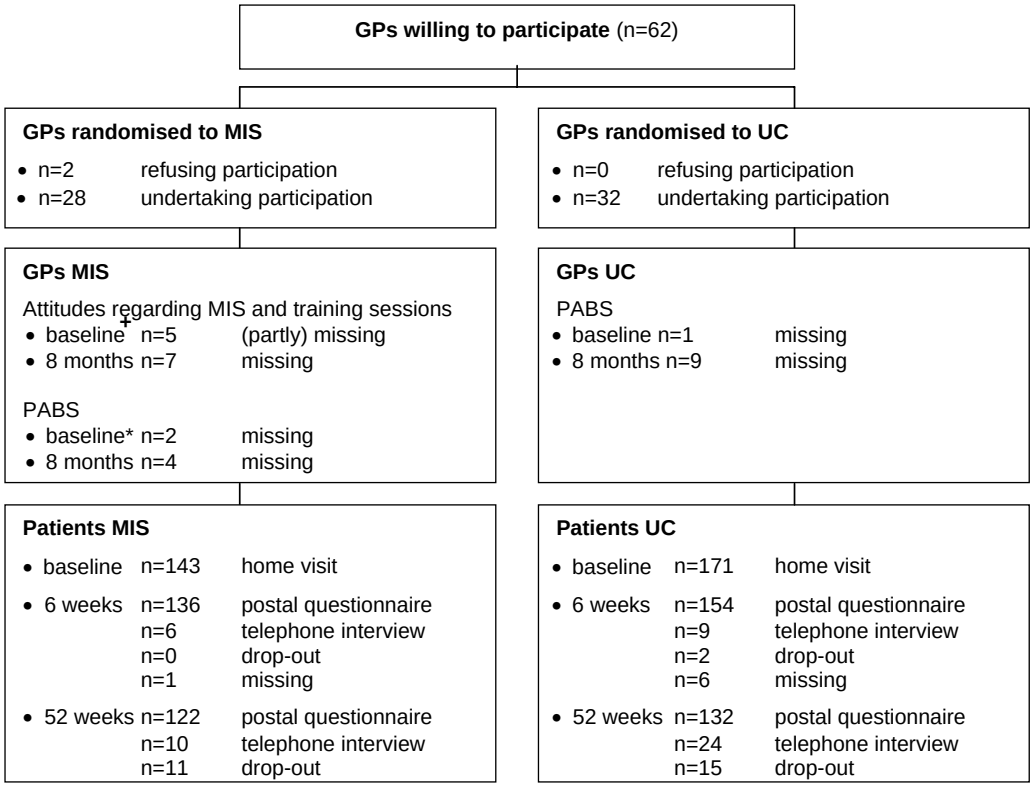
4.4. Modification of psychosocial factors

Change scores for fear avoidance, pain catastrophising and distress for each individual patient were computed by subtracting baseline scores from follow-up scores. Baseline values of the outcome measures were entered as covariate to adjust for any differences between groups at baseline. We performed four subgroup analyses. Three analyses were carried out for patients with elevated baseline scores on psychosocial measures (FABQ>15; CSQ>11; 4DSQ>10). The fourth analysis was only carried out in the MIS-group. Among patients who had an elevated baseline score on a psychosocial measure, change scores were compared between patients who were identified by their GP, versus those not identified.

5. Results

5.1. Study population and baseline characteristics

Between September 2001 and April 2003, 346 patients were willing to participate. After exclusion of 32 patients (no LBP anymore; too old; already treated for LBP by another healthcare professional), 143 patients were enrolled in the MIS-group and 171 in the UC-group. Six patients in the MIS-group did not receive the MIS.



+post-training; *pre-training

Abbreviations: GP= general practitioner; n= number; MIS= Minimal Intervention Strategy; UC= Usual Care; PABS= Pain Attitudes and Beliefs Scale; drop-out= cumulative number of patients who did not return all following questionnaires; missing= number of patients who did not return that specific questionnaire

Fig. 1. Flow chart of general practitioners and patients.

Fig. 1 presents the progress of GPs and patients through our study. As the telephone version of the questionnaire contained only the main outcome measures, data on psychosocial measures were missing for those patients. Table 1 presents demographic details of the GPs and patients who participated in our study. The baseline characteristics are largely similar in both groups.

5.2. GP attitude

The proportion of GPs in the MIS-group who (completely) agreed that MIS was a valuable strategy for treatment of LBP and that the training sessions afforded sufficient skills to apply MIS in practice, was respectively 95% (22/23) and 96.4% (27/28) immediately after the training sessions, and 81% (17/21) and 90.4% (19/21) after the recruitment period.

During the recruitment period the behavioural orientation regarding LBP hardly changed: 0.7 points in the MIS-group (SD 2.5) and 1.1 in the UC-group (SD 3.2). The MD in change between both groups on this subscale (Cronbach's $\alpha = 0.25$) was 0.1 points (95%CI −1.6;1.8). While the score on the biomedical orientation in the MIS-group decreased by 7.3 points (SD 7.5), this score changed by only 0.9 points in the UC-group (SD 5.4). The MD on this subscale (Cronbach's $\alpha = 0.73$) was 6.8

Table 1
Characteristics of general practices, practitioners and patients

		MIS	UC
General practices		$n=20$	$n=21$
Practice setting			
Solo		13/20	11/21
Duo		6/20	6/21
Group		1/20	4/21
Number of registered patients	Mean (SD)	2619 (370)	2700 (523)
Health insurance: % public[a]	Mean (SD)	63.4 (12.0)	60.8 (9.8)
General practitioners		$n=28$	$n=32$
Age[b]	Mean (SD)	43.0 (7.3)	45.7 (7.4)
Gender	Female	6/28	12/32
Years experience as GP[a]	Mean (SD)	13.3 (8.6)	15.3 (9.2)
Number of included patients	Per GP		
0		1/28	5/32
1 thru 5		17/28	14/32
>5		10/28	13/32
Pain Attitudes and Beliefs Questionnaire[c]			
Behavioural orientation (6–36)	Mean (SD)	24.9(3.1)	24.0 (2.9)
Biomedical orientation (14–84)	Mean (SD)	37.0 (6.0)	35.8 (8.2)
Patients		$n=143$	$n=171$
Demographic characteristics			
Age	Mean (SD)	43.4 (11.1)	42.0 (12.0)
Gender	% female	47.6	47.4
Nationality	% Dutch	97.2	97.7
Health insurance	% public	70.6	67.8
Educational level[b]	%		
≤Primary		35.0	33.1
Secondary		46.2	52.7
College, university		18.8	14.2
Paid job	% yes	81.8	81.3
Sick leave because of LBP[b] (among the working population)	% yes	34.8	41.0
Characteristics of LBP			
Duration current episode (days)	Median (IQR)	11 (5–21)	14 (7–21)
Frequency of LBP episodes last year	%		
One or two episodes		58.0	60.8
Three or more episodes		19.6	18.7
Exacerbation of persisting LBP		22.4	20.5
Pain intensity during the day (0–10)[a]	Mean (SD)	4.9 (2.0)	4.8 (2.0)
Pain radiating below knee[b]	% yes	12.8	14.6
Functional disability (RDQ, 0–24)	Mean (SD)	11.7 (5.4)	12.2 (5.0)

Abbreviations: MIS, minimal intervention strategy; UC, usual care; *n*, number; GP, general practitioner; SD, standard deviation; RDQ, Roland-Morris Disability Questionnaire; IQR, inter quartile range; LBP, lower back pain.

[a] $n=1$ missing

[b] $n=2$ missing

[c] $n=3$ missing

Table 2
Identification of psychosocial factors by the GP (MIS-group only)

	Fear avoidance (FABQ)			Catastrophising (CSQ)			Distress (4DSQ)		
	>15	≤15	Mean (SD)	>11	≤11	Mean (SD)	>10	≤10	Mean (SD)
Appraisal by GP									
Obstacle[a]	18	9	16.5 (4.3)	11	4	17.2 (8.5)	13	12	11.5 (6.9)
No obstacle[a]	41	58	13.8 (5.7)	45	59	9.5 (5.8)	26	73	7.5 (6.9)
Sensitivity	30.5%			19.6%			33.3%		
MD [95% CI]			2.7 [0.7;4.7]*			7.7 [2.9;12.5]*			4.0 [0.9;7.0]*

*$P<0.05$. Abbreviations: GP, general practitioner; MIS, minimal intervention strategy; FABQ, fear avoidance and beliefs questionnaire (0–24); CSQ, coping strategies questionnaire (0–36); 4DSQ, four-dimensional symptom questionnaire (0–32); SD, standard deviation; MD, mean difference; CI, confidence intervals.
[a] Obstacle to recovery.

points (95%CI −10.4;−3.2), which was statistically significant.

5.3. GP behaviour

Table 2 presents the results regarding the success of GPs in the MIS-group to identify psychosocial factors. According to the baseline questionnaire 47% (59/126) of the patients showed elevated levels of fear avoidance beliefs; 47% (56/119) of pain catastrophising; and 31% (39/124) of distress, while GPs appraised fear avoidance as an obstacle to recovery in 21% of the patients; pain catastrophising in 13%; and distress in 20%. The sensitivity of the GP appraisal varied between 19.6 and 33.3% (Table 2). However, patients whose fear avoidance, pain catastrophising or distress was appraised by the GP as an obstacle to recovery, had significantly higher scores on that psychosocial measure than patients whose fear avoidance, pain catastrophising or distress was not appraised as obstacle. The MDs were all statistically significant.

Table 3 presents the contents of the treatment as perceived by the patient. In the MIS-group significantly higher proportions reported that they had received an explanation about (i) the cause of LBP; (ii) the factors that can influence their LBP; (iii) the best way to cope with LBP, and that they had received the advice to (i) build up activities in spite of pain; or (ii) to stay active. In the UC-group a significantly higher proportion of the patients reported that they had been referred to a therapist (MIS 20% *v* UC 44%).

Table 3
Patient perspective on treatment, patient satisfaction and compliance

	MIS (*n*)	UC (*n*)	MIS-UC [95%CI]
Evaluation of the contents (yes)			
Physical examination	70.2% (92)	74.0% (114)	−3.8 [−16.3;6.7]
Prescription for medication	47.0% (63)	45.7% (69)	1.3 [−10.3;12.9]
Referral for:			
Therapist	19.8% (26)	43.8% (67)	−24.0 [−34.4;−13.6]*
X-ray	4.0% (5)	5.2% (7)	−1.2 [−6.3;3.9]
Specialist	3.2% (4)	2.3% (3)	0.9 [−3.1;4.9]
Explanation about:			
Cause LBP	82.1% (110)	49.7% (75)	32.4 [22.1;42.7]*
Factors that can influence LBP	79.5% (105)	43.3% (65)	36.2 [25.7;46.7]*
Best way to cope with LBP	85.6% (113)	51.0% (78)	34.6 [24.7;44.5]*
Advise to:			
Build up activities in spite of pain	72.0% (95)	34.4% (52)	37.6 [26.8;48.4]*
Stay active	89.6% (120)	75.7% (115)	13.9 [5.3;22.5]*
Patient satisfaction ((completely) agree)			
My GP showed understanding of my complaints	80.7% (109)	66.9% (103)	13.8 [3.8;23.8]*
I agree with the explanation & advice of my GP	75.6% (102)	69.1% (105)	6.5 [−3.8;16.8]
I am content with the consultation(s)	77.0% (104)	64.3% (99)	12.7 [2.3;23.1]*
Compliance (yes)			
Followed advise to:			
Build up activities in spite of pain	97.9% (93)	94.0% (47)	3.9 [−3.2;11.1]
Stay active	97.5% (115)	95.3% (102)	2.2 [−2.7;7.1]
Read the back book	85.1% (114)	–	–

*$P<0.05$. Abbreviations: MIS, minimal intervention strategy; UC, usual care; *n*, number; CI, confidence interval; LBP, low back pain; GP, general practitioner.

Table 4
Modification of psychosocial factors

	MIS		UC		Mean difference[a] [95% CI]
	Mean (SD)	*n*	Mean (SD)	*n*	
Fear-avoidance (FABQ, 0–24)					
Baseline	14.3 (5.6)	143	15.3 (5.2)	171	
Change score 6 weeks	−2.5 (5.8)	136	−2.2 (5.4)	154	−0.9 [−2.0; 0.3]
Change score 52 weeks	−2.2 (6.1)	120	−2.8 (5.8)	130	−0.2 [−1.5; 1.1]
Catastrophising (CSQ, 0–36)					
Baseline	10.3 (6.6)	143	11.2 (6.9)	171	
Change score 6 weeks	−1.6 (5.2)	136	−2.7 (5.8)	153	0.9 [−0.3; 2.0]
Change score 52 weeks	−3.2 (6.7)	120	−3.7 (6.8)	128	0.0 [−1.5; 1.5]
Distress (4DSQ, 0–32)					
Baseline	8.3 (7.0)	143	9.5 (7.3)	170	
Change score 6 weeks	−2.4 (5.0)	136	−3.6 (6.3)	154	0.7 [−0.5; 1.9]
Change score 52 weeks	−3.4 (5.8)	122	−3.9 (6.2)	130	0.1 [−1.2; 1.4]

Abbreviations: MIS, minimal intervention strategy; UC, usual care; SD, standard deviation; *n*, number; CI, confidence intervals; FABQ, fear avoidance and beliefs questionnaire; CSQ, coping strategies questionnaire; 4DSQ, four-dimensional symptom questionnaire (a higher score means more fear-avoidance beliefs, catastrophising, distress).

[a] MIS-UC, adjusted for baseline values. A mean difference <0 means that the change of the psychosocial measure is larger in the MIS-group than in the UC-group.

5.4. Patient satisfaction and compliance

Table 3 shows that more patients in the MIS-group were satisfied with the treatment than in the UC-group. For two of the three items the difference between the groups was statistically significant. In both groups, a vast majority (> 94%) of the patients reported having been compliant with the GP's advice. In addition, 85% of the patients in the MIS-group reported having read the booklet on LBP.

5.5. Modification of psychosocial factors

Table 4 presents the mean scores on fear avoidance beliefs, pain catastrophising and distress at baseline and after 6 and 52 weeks, and also the adjusted MDs between the treatment groups for changes on these measures. The adjusted MD for fear-avoidance beliefs (FABQ) was −0.9 points (95%CI −2.0;0.3) at 6 weeks and −0.2 points (95%CI −1.5;1.1) at 52 weeks. Both MDs slightly favoured MIS. All differences between groups in Table 4 were small and not statistically significant. Also, in subgroups of patients with an elevated baseline score on a psychosocial measure the differences between MIS and UC were small and not statistically significant (data not shown).

Table 5 presents the results of the subgroup analysis for patients in the MIS-group who had an elevated score on a psychosocial measure according to the baseline questionnaire. There were no statistically significant differences in

Table 5
Modification of psychosocial factors among patients having an elevated score according to the baseline questionnaire. Comparison of patients identified by the GP and those not identified (MIS-group only)

	Patients identified by GP		Patients NOT identified		Mean difference[a] [95% CI]
	Mean (SD)	*n*	Mean (SD)	*n*	
Fear-avoidance (FABQ, 16–24)					
Baseline	18.8 (1.8)	18	19.1 (2.3)	41	
Change score 6 weeks	−5.1 (6.3)	17	−4.6 (5.1)	39	−0.4 [−3.6; 2.8]
Catastrophising (CSQ, 12–36)					
Baseline	21.3 (5.0)	11	15.2 (2.6)	45	
Change score 6 weeks	−2.4 (4.1)	10	−4.1 (5.4)	43	1.7 [−1.9; 5.4]
Distress (4DSQ, 11–32)					
Baseline	17.0 (4.0)	13	17.2 (5.2)	26	
Change score 6 weeks	−4.8 (7.2)	12	−5.7 (7.1)	23	0.9 [−4.2; 6.0]

Abbreviations: GP, general practitioner; MIS, minimal intervention strategy; SD, standard deviation; *n*, number; CI, confidence intervals; FABQ, fear avoidance and beliefs questionnaire; CSQ, coping strategies questionnaire; 4DSQ, four-dimensional symptom questionnaire (a higher score means more fear-avoidance beliefs, catastrophising, distress).

[a] A mean difference <0 means that the change of the psychosocial measure is larger in the group identified by the GP than in the group not identified by the GP.

changes on psychosocial measures between patients who were identified by their GP as having an obstacle to recovery and those not identified.

6. Discussion

This study tried to identify process variables that may have contributed to the fact that we found no effect of MIS over UC. Our 'post-mortem' analysis showed that these findings may be explained especially by a suboptimal identification of patients with elevated scores on psychosocial measures by GPs in the MIS-group, and a lack of modification of psychosocial factors.

6.1. Training sessions

Training sessions were aimed at changing GP attitudes and behaviour. Results on attitudes show that GPs believed in the new strategy and in their competency to carry out MIS. Both seem to be important when introducing a new intervention. However, as we only measured the opinions of GPs and not their acquired skills, social desirability may have biased these results. The attitudes of the trained GPs regarding (treatment of) LBP did change away from a biomedical orientation, although not towards a more behavioural orientation as we expected beforehand. One of the explanations may be that our training sessions were sufficient to unlearn their 'old' biomedical orientation, but too minimal to gain the new behavioural orientation. However, the poor internal consistency of the behavioural subscale (Cronbach's $\alpha = 0.25$) prevents drawing firm conclusions regarding the results of this subscale.

A change in attitude does not necessarily lead to a change in behaviour. In the training sessions GPs were taught to identify psychosocial factors like fear avoidance, pain catastrophising and distress. When analyses were performed on a group level, GPs seemed able to identify the group of patients with an elevated score of a psychosocial measure at baseline, although one may debate the clinical relevance of the mean differences between groups. When analyses were performed on a patient level, however, GPs seemed less able to identify individuals with elevated scores on psychosocial measures. The proportion of patients who had an elevated score at baseline and were identified by their GP (i.e. sensitivity), was low (range 13–21%). Although we used validated questionnaires we lacked a validated cut-off for two psychosocial measures. Only for the 4DSQ a clinically validated cut-off score for a general practice population was available (Terluin et al., 2004). For both the FABQ and the CSQ we used the medians as cut-off score, by definition leading to 50% elevated scores. One may propose that not all of these patients had levels of fear avoidance or pain catastrophising that are clinically relevant, and argue that GPs may be better at identifying high levels of fear avoidance than a questionnaire because they use a higher 'cut-off'. To explore this we performed sensitivity analyses for the three psychosocial measures using the 75th percentile scores as cut-off score. An increase of the sensitivity of the GP appraisal would confirm the proposition that GPs used a higher 'cut-off'. However, the sensitivity dropped from 30.5 to 21.4% for fear avoidance, while it hardly changed for distress (33.3 *v* 35.5%). Although sensitivity rose from 19.6 to 35.5% for pain catastrophising, this still indicates low sensitivity. GPs did thus not identify those with the highest scores on psychosocial measures, and therefore, we conclude that GPs in the MIS-group were only moderately successful in identifying those factors.

GPs were also trained in providing evidence-based care. The reasons for encounter that were demonstrated by Schers et al. (2001) as important (i.e. obtaining a diagnosis and advice on how to facilitate improvement) were substantially more often addressed in the MIS-group than in the UC-group. Besides, substantially more patients in the MIS-group reported having received the advice to build up activities in spite of pain, and to stay active. The first advice is a typical 'anti fear-avoidance' advice and was practiced in the training sessions. The second advice is also mentioned in the guideline for LBP of the Dutch college of general practitioners (Faas et al., 1996). In the UC-group, 76% of patients reported having received the advice to stay active, which is the same (Schers et al., 2000) or somewhat lower (Engers et al., 2005) than presented by studies on implementation of this guideline. Whether these recommendations have actually led to a change in behaviour of patients is unknown, but may be questioned as changing behaviour is a challenging task, possibly requiring more time and effort than available in our MIS. Less favourable were the results in the MIS-group regarding referral to a physical therapist. Although the referral rate was only half of that in the UC-group, a rate of 20% is still substantial as GPs in the MIS-group were explicitly asked not to refer during the first 6 weeks. Although we do realise that our method is not the optimal way to establish the exact contents of treatment, we may conclude that there was a contrast between both groups regarding evidence-based care.

Five hours of training did not lead to sufficient GP competency with regard to identification of psychosocial factors. May be more hours of training would have led to better results, just as feedback sessions to reinforce learning. One may question the use of GPs delivering psychosocial interventions. A Cochrane review has shown that there is, as yet, little evidence to support or refute the use of psychosocial interventions by GPs (Huibers et al., 2003). Consequently, it is too early to determine whether GPs should or should not deliver psychosocial interventions.

6.2. Patient satisfaction and compliance

More patients in the MIS-group were satisfied with care than in the UC-group, although one may debate the

relevance of this rather small difference. This difference in favour of MIS may have been caused by the contents of MIS, but also by the longer duration of the consultation. With regard to compliance social desirability has probably influenced our findings to such an extent, that no firm conclusions can be drawn.

6.3. Modification of psychosocial measures

As MIS did not lead to better functioning than UC (Jellema et al., 2005), the fact that we found no significant differences in changes of psychosocial measures between groups is in agreement with our theory on the working mechanisms of MIS. The absence of modification of psychosocial factors can be explained in several ways. Firstly, the suboptimal identification of psychosocial factors by GPs in the MIS-group may have hindered modification and reduced the contrast between the intervention groups. Furthermore, GPs in the UC-group may also have addressed psychosocial factors, reducing the contrast even more. Audiotaping of the consultations in both groups could have confirmed these assumptions, but was, unfortunately, not feasible in this large scale trial.

Secondly, as about 70% of the patients in the MIS-group had only one 20 min consultation in which psychosocial issues were assessed and discussed (Jellema et al., 2005), MIS may have been insufficiently intensive to influence or restructure dysfunctional thoughts and beliefs about LBP. This explanation is supported by the analyses we performed in the subgroups of patients whose scores on psychosocial measures were elevated at baseline. As the scores in both the MIS and UC groups were still elevated at follow-up (data not shown), and as it did not seem to matter whether MIS patients were identified by their GP or not, one may hypothesize that for these patients a more intensive intervention strategy could have been successful. Some studies using more intensive psychosocial, early group interventions have demonstrated positive effect on psychosocial measures (George et al., 2003; Moore et al., 2000; Von Korff et al., 1998), while others were unable to do so (Linton and Andersson, 2000).

A third explanation may be that we have failed to measure the process adequately by using measures that were not sufficiently responsive and/or by using an inadequate duration of follow-up. Both treatment groups did improve on all psychosocial measures during follow-up. In our opinion, a follow-up of 6 weeks seems appropriate to pick up the effects of a minimal intervention strategy. To explore changes in psychosocial factors more precisely we could have assessed the psychosocial measures more frequently in the first 6 weeks, especially as about 60% reported recovery within 6 weeks (Jellema et al., 2005).

Our study showed that providing targeted information on psychosocial factors to patients with (sub)acute LBP in general practice may not lead to modification of fear-avoidance beliefs, pain catstrophising or distress.

6.4. Recommendations

We recommend researchers planning a randomised trial evaluating a complex intervention to assess process measures on several levels (e.g. caregiver and patient). By doing this, the researcher may be able to explore why an intervention did (not) work and may, thereby, contribute to theory formation.

Future research could be aimed at the development and validation of methods for studying process measures, such as methods to assess caregivers' attitudes, knowledge and behaviour. A second topic of research could be the establishment of clinically validated cut-off scores for questionnaires. Lastly, research could be aimed at the development and validation of instruments that are convenient to diagnose fear avoidance beliefs, pain catastrophising and distress in everyday general practice.

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